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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,999	10/04/2005	Hasse Roland Abrahamsson	056291-5214	6477
9629 7590 03/04/2008 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				
EXAMINER				
SPIVACK, PHYLLIS G				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
03/04/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/551,999

**Applicant(s)**

ABRAHAMSSON ET AL.

**Examiner**

Phyllis G. Spivack

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4, 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 8, 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

Applicants' Amendment filed December 10, 2007 is acknowledged. Claims 1-3 and 5-7 are canceled. New claims 8 and 9 are presented. Accordingly, claims 4, 8 and 9 are presently under consideration.

Applicants' arguments have been fully considered. Rejections and/or objections not herein reiterated are hereby withdrawn. The rejections and objections set forth below constitute the only ones applied to the present claims.

A new Abstract and an amended title are noted.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The present claims are not drawn to "prophylaxis."

The disclosure is objected to for the following informalities: The term "hydrolyzable" is incorrectly spelled twice at the end of claim 4.

Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindquist, A-M, US 2005/0124557, in view of Starke et al., U.S. Patent 7,132,416.

Lindquist suggests pharmaceutical compositions comprising IBAT (ileal bile acid transport) inhibitors may be employed for a laxative effect. See page 1, paragraph [0005]. Although Lindquist's teaching encompasses any and all compounds that

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function as IBAT inhibitors (page 1, paragraph [0006]), the reference fails to recite the specific IBAT inhibitors that are instantly claimed. However, all such IBAT inhibitor compounds are specifically taught by Starke.

Therefore, in view of the combined teachings of Lindquist and Starke, one skilled in the gastroenterology art would have been motivated to employ an IBAT inhibitor to treat functional constipation or constipation-predominant irritable bowel syndrome. Such would have been obvious in the absence of evidence to the contrary because the symptomatology to be treated in both instances is the same. Both conditions are characterized by dysfunction of motility, discomfort and difficulty in the passage of feces. Functional constipation may be the result of a poor diet, a psychological or psychosomatic background or decreased muscle activity in the colon. Therefore, those skilled in the art would have reasonably been motivated to administer compounds exhibiting a laxative effect, such as IBAT inhibitors, to treat functional constipation or constipation-dominant irritable bowel syndrome with a reasonable expectation of success.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614

February 21, 2008

Phyllis G. Spivack

**Application Number****Application/Control No.**

10/551,999

**Applicant(s)/Patent under  
Reexamination**

ABRAHAMSSON ET AL.

**Examiner**

Phyllis G. Spivack

**Art Unit**

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